

REMARKS

Claims 22-46 are pending in this application. By this Amendment, new claims 42-46 are added and claim 22 is amended to overcome the rejection under 35 U.S.C. §112 as set forth in the Office Action.

No new matter is added to the application by this Amendment. Support for new claims 42-46 is found in canceled features of claim 22.

Reconsideration of the application is respectfully requested.

I. Information Disclosure Statements

Applicants filed a first Information Disclosure Statement (IDS) on March 28, 2006 and a second IDS on December 21, 2006. With respect to the March 28, 2006 IDS, cited Documents AA-AG were not initialed by the Examiner. With respect to the December 21, 2006 IDS, the Non-Patent Literature Document to Guido Schnyder et al. was not initialed by the Examiner. Thus, Applicants have enclosed, for the convenience of the Patent Office, a copy of the PTO Forms-1449 from the March 28, 2006 IDS and the December 21, 2006 IDS. Applicants request that the Examiner initial the cited Documents AA-AG and Guido Schnyder et al. in the attached PTO Forms-1449 indicating that those references were considered by the Patent Office before the mailing of the March 4, 2008 Office Action. Moreover, Applicants request that the Examiner return an initialed copy of the PTO Forms-1449 to Applicants' representative by facsimile communication to (212)808-0844.

II. Rejection Under 35 U.S.C. §112

Claims 22-41 were rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicants regard as the invention. This rejection is respectfully traversed.

The Patent Office alleges that claims 22-41 recited indefinite language as set forth in the following phrases: “such as a staple or rivet”; “in particular a puncture”; “such as oxides”; “such as colloidal particles”; and “such as soluble salts”. The Patent Office also alleges that it is unclear whether these phrases limit the scope of the claims or merely suggest possible embodiments within the scope of the claims.

Claim 22 has been amended to remove the above-identified phrases therefrom. The subject matter of the phrases removed from claim 22 is retained in new claims 42-46.

Applicants submit that amended claim 22 is definite and clear such that one of ordinary skill in the art may identify the subject matter which Applicants regard as their invention.

Thus, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

III. Rejection Under 35 U.S.C. §103

Claim 22-41 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,506,210 to Kanner in view of U.S. Patent No. 6,287,332 to Bolz et al. (hereinafter “Bolz”). The rejection is respectfully traversed.

The presently claimed member is for closing a wound caused by a puncture and made of a bioresorbable and/or biodegradable material, i.e. a material which is transformed in the neighbouring tissue in which it is implanted so that it can be dispersed throughout the body and/or eliminated without being detectable in the neighbouring tissue. In contrast, the staples according to Kanner are made of biocompatible or bioabsorbable materials, which both permanently remain in the neighbouring body tissue without undergoing any major structural

changes. (See page 3, line 21 – page 4, line 3 and page 6, line 15 – page 7, line 9 of the present Application).

The Patent Office acknowledges that Kanner does not disclose a staple made of a bioresorbable material (see page 3 of the Office Action). The Patent Office introduces Bolz as allegedly disclosing a bioresorbable material which is transformable in the tissue into smaller elements such as colloidal particles. Moreover, the Patent Office alleges that it would have been obvious to modify the apparatus of Kanner by having the staple be made of bioresorbable materials disclosed in Bolz in order for the staple to have desirable bioresorptive properties as taught by Bolz. Applicants disagree with the allegations.

Kanner discloses a staple is made of “biocompatible and/or bioabsorbable materials” (see col. 4, lines 36 of Kanner). These materials of the Kanner staple include “titanium (and titanium alloys), stainless steel, polymeric materials (synthetic and/or natural), ceramic, etc.” The materials of the Kanner staple will “permanently remain in the local body tissue without undergoing any major structural changes”. In other words, when the Kanner staple is used to close a wound in a tissue caused by a puncture, the materials of the Kanner staple are slowly and permanently incorporated into the neighbouring body tissue leading to the presence of a foreign composition in this tissue which may permanently alter the tissue’s properties.

Kanner clearly teaches a material for staples having physical characteristics (i.e., biocompatible and/or bioabsorbable) that are completely opposite to the physical characteristics (i.e., bioresorbable and biodegradable) of the material for the presently claimed member. Thus, Kanner would not have provided one having ordinary skill in the art with a teaching, suggestion or incentive to modify the disclosed biocompatible and/or bioabsorbable composition in order to

provide a member made of a bioresorbable material (transformable into smaller elements that remain in said body as traceable elements) or biodegradable material (transformable into smaller elements that remain in surround tissue as fine undetectable precipitates or that dissolve and are ultimately eliminated from said body) as required by claim 22.

Contrary to the allegations by the Patent Office Bolz does not remedy the deficiencies of Kanner because Bolz fails to teach or suggest a member for urging together two or more portions of tissue of a body and maintaining the portions together until the portions are secured together by scarring thereof, wherein the member is made of a bioresorbable material and/or a biodegradable material. Bolz merely discloses a vessel wall support, in particular a coronary stent which is made of the a bioresorbable material. Bolz clearly fails to disclose a member for urging together two or more portions of body tissue which portions form a wound caused by a puncture until the portions are secured together by scarring thereof as required in claim 22.

In fact, Bolz teaches away from the presently claimed members because Bolz discloses stents that are made of bioresorbable material which are used to avoid restenosis. In other words, the Bolz stents prevent scarring of the internal vessel walls against which the stent is placed. Additionally, the disclosure of Bolz would not have lead one of ordinary skill in the art to believe that the bioresorbable materials of Bolz would allow scarring of an injured tissue against which it would be placed. Further, one of ordinary skill in the art would have every reason to believe that the bioresorbable materials in accordance with the teachings of Bolz would inhibit scarring of injured tissue. Thus, Bolz teaches away from using biodegradable and/or bioresorbable materials to scar injured tissue portions by placing the biodegradable and/or bioresorbable material directly against the injured part of the tissue.

One of ordinary skill in the art would not have been led to use the bioresorbable materials disclosed in Bolz as an alternative material for manufacturing Kanner's staple, but would have been led away therefrom in accordance with the teachings of Bolz. Moreover, Bolz would not have provided one of ordinary skill in the art with a teaching, suggestion or incentive to provide a member for urging together two or more portions of body tissue which portions form a wound caused by a puncture and maintaining the portions together until the portions are secured together by scarring thereof, wherein the member is made of a bioresorbable material and/or a biodegradable material as recited in claim 22.

Thus, neither Kanner nor Bolz, taken singly or in combination, teaches or suggests a member for urging together two or more portions of tissue of a body which tissue portions form a wound caused by a puncture and maintaining the portions together until the portions are secured together by scarring thereof, wherein the member is made of a material selected from at least one of metals, alloys and ceramic compounds thereof, the material being (1) a bioresorbable material which is transformable in the tissue into smaller elements that remain in the body as traceable elements and/or (2) a biodegradable material which is transformable in the tissue into smaller elements that remain in surround tissue as fine undetectable precipitates or that dissolve and are ultimately eliminated from the body as required by claim 22.

Because these features of independent claim 22 are not taught or suggested by Kanner and Bolz, Kanner and Bolz would not have rendered the features of claims 22-41 obvious to one of ordinary skill in the art.

For at least these reasons, claims 22-41 are patentable over the applied references. Thus, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

IV. New Claims

In view of all the foregoing reasons, new claims 42-46 are patentable over the applied references because Kanner and Bolz, taken singly or in combination, fail to teach or suggest the required features of claim 22 from which new claims 42-46 depend from.

V. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1 and 3-37 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

Respectfully submitted,

NORRIS MCLAUGHLIN & MARCUS, P.A.

By /Brian C. Anscomb/
Brian C. Anscomb
Attorney for Applicants
Reg. No. 48,641
875 Third Avenue, 18th Floor
New York, NY 10022
Tel. 212-808-0700